REMARKS

In paragraph 2, on page 2 of the Office Action, the Examiner rejects Claims 107-128 under 35 U.S.C. § 112, first paragraph for failing to comply with the written description requirement.

Specifically, the Examiner states that the language "about 17-28 nucleotides in length" in defining the size of the oligonucleotide lacks support in the specification.

For the following reasons, Applicants respectfully traverse the Examiner's rejection.

The Examiner is requested to note the lengths of the oligonucleotides are disclosed in Tables 4-8 of the present application. For example, Tables 4, 5 and 5A list oligonucleotides that are 17, 18, 19 22 or 28 nucleotides in length, for example, forward primer #1070, reverse primer #1069, reverse primer #1071, reverse primer #1081, and reverse primer #871, respectively. This disclosure indicates that Applicants contemplated using oligonucleotides that ranged from "about 17 to 28 nucleotides in length" as of the effective filing date of the present application. Thus, Applicants respectfully submit that the Examiner's contention that there is no support for such oligonucleotides is in error, and hence the rejection should be withdrawn.

The Examiner contends that the recitation of these primers does not provide adequate written support for a range of oligonucleotides that are to be used in a classical hybridization assay.

Applicants respectfully submit that the claims are directed to a method of testing a sample for the presence of a given bacterial serotype that relies on the principle of hybridization for target identification. The oligonucleotides of the claimed method are about 17-28 nucleotides in length. Thus, the range of oligonucleotides that are to be used in the claimed method will be oligonucleotides of about 17-28 nucleotides in length that will identify a target sequence by means of the principle of hybridization.

Applicants respectfully submit that the specification demonstrates the specificity for the target sequences conferred by the exemplified oligonucleotides. This specificity is achieved through hybridization of the oligonucleotides to the target sequences. It must be stressed that it is the step of hybridization itself that confers specificity in a PCR assay, provided that the oligonucleotide sequence is specific for the target sequence. Therefore, given that the oligonucleotides as recited in the claims are specific for the intended target sequences, Applicants are entitled to claim any hybridization assay that utilizes the oligonucleotides as recited in the claims for specific sequence targeting, relying on the specificity of the oligonucleotides to provide the specific hybridization required to achieve a meaningful result in the assay. Thus, the oligonucleotides as recited in the claims are clearly applicable to hybridization assays other than those requiring an amplification step.

All hybridization assays necessarily rely on the specificity of probe sequence, and Applicants have successfully

exemplified to the person skilled in the art a set of oligonucleotides that have demonstrated use for target selectivity based on the principle of selective hybridization. The oligonucleotides exemplified in the present specification have been amply demonstrated in the present specification to possess specificity of sequence for the target serotypes. Applicants wish to emphasize this fact, in view of the Examiner's contention, below, that the primers disclosed in Tables 4-7 are non-functional.

The Examiner contends that Tables 4-7 show that virtually none of the primers yielded an amplicon of the correct size. It appears that the Examiner has interpreted the absence of amplicons of the correct size in various serotype pools tested as evidence that the oligonucleotide primers do not work.

Applicant respectfully submits that the Examiner has misinterpreted the data. The value of zero appearing in the column designated "NUMBER OF POOLS GIVING BAND OF CORRECT SIZE" is indicative that for the designated gene sequence, no bacteria in the given pool of serotypes resulted in a PCR amplicon of the expected size, the test pools consisting of bacterial DNA of various serotypes excluding DNA of the target serotype. Thus, the absence of an amplicon in test pools, and the presence of a correctly sized amplicon in the positive control pools containing the target sequence (see for example page 42, lines 34-36 through to page 43, line 4) confirms the specificity of the oligonucleotides for the target sequences. In other words, the absence of an amplicon of the correct size in test pools and the presence of amplicons in positive control pools

demonstrates that the oligonucleotides do not detect serotypes other than the intended targets. Even where amplicons were evident, but of incorrect size, the absence of correctly sized amplicons is evidence of the absence of the target gene sequence as manifest in the target serotype, that is, absence of the target serotype. The Examiner's attention is drawn to the disclosure of Tables 1-3, and the text at pages 40-48 under the heading " Materials and Methods - part 4".

Applicants respectfully submit, therefore, that the oligonucleotides of the present invention are indeed functional, and that the specification provides ample support for oligonucleotides of "about 17 to 28 nucleotides" in length.

Furthermore, Applicants are entitled to claim the use of the oligonucleotides as recited in the claims in hybridization assays other than those involving an amplification step, the fundamental principle of such assays being the provision of nucleotide sequences that are target-specific.

Accordingly, Applicants respectfully submit that the claims have written description support in the specification, and thus request withdrawal of the Examiner's rejection.

In view of the arguments set forth above, reexamination, reconsideration and allowance are respectfully requested.

The Examiner is invited to contact the undersigned at his Washington telephone number on any questions which might arise.

Respectfully submitted,

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